K062800

510 (k) Summary

1. Company Information

Company name	TaiDoc Technology Corporation
Contact person	Pi-Shiou Li
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Phone	886-2-6635-8080
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2. Device Identification

Trade name	Clever Chek TD-3213 Blood Glucose plus Blood Pressure Monitoring System
	Clever Chek TD-3215 Blood Glucose plus Blood Pressure Monitoring System
	Dr. T TD-3216 Blood Glucose plus Blood Pressure Monitoring System
	Clever Chek TD-3217 Blood Glucose plus Blood Pressure Monitoring System
	Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring System
Common name	Blood Glucose and Blood Pressure Measurement System
	Blood Glucose Test Strip
Classification name	Class II devices
	21 CFR Section 862.1345, Glucose Test System
	21 CFR Section 870.1130, Non-invasive Blood Pressure Measurement System

3. Predicate Device

K061181	ACHTUNG Blood Glucose Monitoring System by TaiDoc Technology Corporation.
K042795	Clever Chek TD-3213 Blood Glucose and Blood Pressure Measurement System by TaiDoc Technology Corporation.
K061073	Clever Chek TD-3250 Blood Glucose and Blood Pressure Measurement System by TaiDoc Technology Corporation.

4. Device Description

The Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216/ Clever Chek TD-3217/ Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring System consists of a monitor with wrist/arm cuff and test strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions.

The system is able to provide blood pressure measurement which adopts the "oscillometric method" as the measuring principle. It provides the systolic pressure, diastolic blood pressure and pulse rate on an adult individual, over age 16, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist (Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216/ Clever Chek TD-3217) or in the arm (Clever Chek TD-3250). The cuff circumference is limited to 5.25" ~7.75" (13 ~20 cm) for wrist or 9.4"~13.8" (24 ~35 cm) for arm.

5. Intended Use

The Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216/ Clever Chek TD-3217/ Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring System is indicated for the quantitative measurement of glucose in fresh whole blood (capillary blood from the finger, the palm, the forearm, the upper-arm, the calf and the thigh) for self testing by persons with diabetes in the home or by healthcare professionals in healthcare facilities. Testing is done outside the body (in vitro diagnostic use).

The system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual, over age 16, at home.

For Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216/ Clever Chek TD-3217 system, the blood pressure is measured by using a technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 5.25" ~ 7.75".

For Clever Chek TD-3250 system, the blood pressure is measured by using

a technique in which an inflatable cuff is wrapped around the arm. The cuff circumference is limited to 9.4" ~ 13.8".

6. Comparison to Predicate Device

   The Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216/ Clever Chek TD-3217/ Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring System has equivalent technological characteristics as the ACHTUNG Blood Glucose Monitoring System (K061181), the Clever Chek TD-3213 Blood Glucose and Blood Pressure Measurement System (K042795) and the the Clever Chek TD-3250 Blood Glucose and Blood Pressure Measurement System (K061073).

   The system also contains the same intended use as the ACHTUNG Blood Glucose Monitoring System (K061181), the Clever Chek TD-3213 Blood Glucose and Blood Pressure Measurement System (K042795) and the the Clever Chek TD-3250 Blood Glucose and Blood Pressure Measurement System (K061073).

7. Performance Studies

   The performance of the Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216/ Clever Chek TD-3217/ Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring System was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that the above blood glucose plus blood pressure monitoring system is suitable for its intended use.

8. Conclusion

   The Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216/ Clever Chek TD-3217/ Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring System demonstrates satisfactory performance and is suitable for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 31 2007

Taidoc Technology Corporation
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San Chung, Taipei 241
China (Taiwan)
ATTN: Ms. Pi-Shiou Li

Re: k062800
Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216/Clever Chek TD-3217/ Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, DXN
Dated: December 28, 2006
Received: January 03, 2007

Dear Ms. Li:

This letter corrects our substantially equivalent letter of January 22, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K062800

Device Name: Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216 Clever Chek TD-3217/Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring System

Indications for Use:

The Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216/Clever Chek TD-3217/ Clever Chek TD-3250 Blood Glucose plus Blood Pressure Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The alternative site testing in the systems can be used only during steady-state blood glucose conditions.

The system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual, over age 16, at home.

For Clever Chek TD-3213/ Clever Chek TD-3215/ Dr. T TD-3216/ Clever Chek TD-3217 system, the blood pressure is measured by using a technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 5.25" ~ 7.75".

For Clever Chek TD-3250 system, the blood pressure is measured by using a technique in which an inflatable cuff is wrapped around the arm. The cuff circumference is limited to 9.4" ~ 13.8".

Prescription Use __X____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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